

### REMARKS

This Application has been carefully reviewed in light of the Final Office Action mailed November 3, 2005. At the time of the Final Office Action, Claims 1-6, 17 and 37-61 were pending in this Application. Claims 2-6, 17 and 37-56 were rejected. Claims 1 and 57-61 were allowed. Claims 7-16 and 18-36 were previously cancelled without prejudice due to an election/restriction requirement. Claims 7-56 are now cancelled. Claims 2, 3 and 5 have been amended to further define various features of Applicants' invention. Claims 62-68 have been added. No new matter is presented by these amendments. Applicants respectfully request reconsideration and favorable action in this case.

#### **Rejections under 35 U.S.C. § 112 - Enablement**

Claims 2-6, 17 and 37-56 were rejected by the Examiner under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1, does not reasonably provide enablement for sequences having less than 100% sequence identity to SEQ ID NO: 1. Applicants amend Claims 2, 3 and 5 to overcome these rejections.

Specifically, Applicants have amended Claims 2, 3 and 5 to recite promoters at least 98% homologous to SEQ. ID. NO. 1. Applicants believe that it, despite the large number of bases in SEQ. ID. NO. 1, it would not be unduly burdensome for one skilled in the art to test variants that would remain at least 98% homologous. Additionally, while the Examiner is correct that degenerate code and conservative substitution considerations do not apply to promoters, Applicants assert that similar guiding knowledge is available in the context of promoters. In particular, it is well known that certain promoter regions may not be changed without severely interfering with promoter activity. For example, the TATA box is required for an effective promoter. This box and as well as the CAT box are indicated in Figure 1. (See Figure 1 and p. 10, lines 14-15.) Initiator regions are also of known importance. One skilled in the art would recognize that changes in important regions, such as the TATA box, are likely to produce nucleic acids not capable of functioning as a promoter. Thus, one skilled in the art would likely avoid changes in those regions.

In short, the existence of regions necessary for promoter activity actually further limits the number of variant promoters one skilled in the art might test and thus makes testing more manageable and routine.

Applicants believe similar arguments apply to new claims 62-68, which are directed to a functional fragment of SEQ. ID. NO. 1.

**Rejections under 35 U.S.C. § 112 - Written Description**

Claims 2-6, 17 and 37-56 were rejected by the Examiner under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants amend Claims 2, 3 and 5 to overcome these rejections.

Applicants have amended the claims to recite a nucleic acid having a sequence 98% homologous to SEQ. ID. NO. 1. Thus greatly reduces the number of species in the genus as compared to the 60% discussed by the Examiner in the Office Action. Further, as explained above, there are conserved promoter regions very likely to be present in or even required to be in allelic variants and other mutants that are able to function as a promoter. Thus, the genus as currently claimed is far closer to the situation of *Capon* and less like that of *Eli Lilly*, where there was a much more substantial difference in homology between rat insulin and human insulin.

Applicants believe similar arguments apply to new claims 62-68, which are directed to a functional fragment of SEQ. ID. NO. 1.

**Allowable Subject Matter**

Claims 1 and 57-61 were allowed. These claims are not amended in the current response.

**Information Disclosure Statement**

Applicants enclose an Information Disclosure Statement and PTO Form 1449, with copies of the references for the Examiner's review and consideration. Applicants believe no fees are due with this Information Disclosure Statement because Applicants are filing a Request for Continued Examination (RCE).

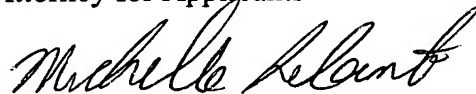
**CONCLUSION**

Applicants have now made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicants respectfully request reconsideration of the claims as amended.

Applicants enclose a Request for Continued Examination (RCE) and a check in the amount of \$395.00 for the RCE fee. Applicants also enclose a Petition for One Month Extension of Time and a check in the amount of \$60.00 for the extension fee. Applicants believe no further fees are due, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 02-0384 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicants' attorney at 512.322.2580.

Respectfully submitted,  
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Date: 3/2/06

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